1 (Amended Twice) A medical device comprising a composite having an inorganic substrate and a polymer covering at least a portion of the substrate, the polymer forming a structure substantially different from the structure of the substrate, and providing the form of the device.

32. (New) The medical device of claim 1 wherein the polymer is rigid.

REMARKS

In response to the Office Action dated August 14, 2002, claim 1 has been amended and new claim 32 has been added. Support for the amendment to claim 1 can be found, for example, on page 4, lines 25-31. Support for new claim 32 can be found, for example, on page 18, lines 31-33. No new matter has been added. Claims 1-3, 5-20 and 31-32 are pending in the application. Reconsideration of the claims is respectfully requested.

Rejection under 35 U.S.C. §102

I. In paragraph 4 on page 2 of the Office Action, claims 10-17 remain rejected under 35 U.S.C. §102 (b) as being anticipated by Pietsch, et al. (U.S. 4,778,461). Applicants respectfully traverse this rejection.

To anticipate a claim, the reference must teach every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Therefore, all claim elements, and their limitations, must be found in the prior art reference to maintain a rejection based on 35 U.S.C. §102.

As previously discussed, the Pietsch patent does not disclose a composite that can be bent at least about 100 degrees without extending the material beyond its elastic limit, as follows:

1. In Pietsch, the cusps are flexible, but they are not made of a substrate and polymer composite. See col. 3, lines 35-40.

2. As characterized by the Examiner, the support ring is taught to be deformable elastically. However, as taught in Pietsch, deformable elastically is not the same as flexible. This is made clear by Pietsch that the support ring "supports only the lower part of the valve, whereas the upper part of the cusps and their joining zones (the commissure) remains free and flexible." Col. 1, lines 60-68. While Pietsch also taught that metals and ceramics are used for the support ring, as also noted by the Examiner, nevertheless, there is no teaching that the support ring comprises a flexible substrate and polymer composite.

On the other hand, claims 10-17 refer to the bending of both components of the composite, the substrate and the polymer. Applicants respectfully submit that Pietsch does not teach the subject matter of claims 10-17. Applicants request that the rejection under 35 U.S.C. §102 (b) as being anticipated by Pietsch, et al. (U.S. 4,778,461) should be withdrawn.

II. In paragraph 8 on page 3 of the Office Action, claims 1-2, 5, and 8 are rejected under 35 U.S.C. §102 (b) as being anticipated by Cromie (U.S. 3,722,004). Applicants respectfully traverse the rejection.

As characterized by the Examiner, Cromie teaches struts made of metal (titanium) coated with carbon, which hold a disc for an occluder disc type heart valve, and an inorganic substrate (ring) of hard, wear-resistant metal (titanium) embedded in a plastic matrix with the outer circumference of the ring protruding from the plastic (abstract, col. 1, lines 45-68). The plastic matrix is made of polycarbonate (col. 2, lines 1-10) which is a rigid polymer.

On the other hand, claim 1 as amended, discloses a medical device comprising a composite having an inorganic substrate and a polymer covering at least a portion of the substrate, forming a structure substantially different from the structure of the substrate and providing the form of the device.

As noted above, to anticipate a claim, the reference must teach every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Therefore, all claim elements, and their limitations, must be found in the prior art reference to maintain a rejection based on 35 U.S.C. §102. Applicants respectfully submit that Cromie does not teach every element of claim 1, and therefore fails to anticipate these claims. Applicants request that the rejection under 35 U.S.C. §102 (b) as being anticipated by Cromie (U.S. 3,722,004) be withdrawn.

Dependent claims 2, 5 and 8, which are dependent from independent claim 1 were also rejected under 35 U.S.C. §102(b) as being unpatentable over Cromie. While Applicants do not acquiesce with the particular rejections to these dependent claims, it is believed that these rejections are moot in view of the remarks made in connection with independent claim 1. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. Therefore, dependent claims 2, 5 and 8 are also in condition for allowance.

Rejection under 35 U.S.C. § 103(a)

I. In paragraph 5 on page 3 of the Office Action, claims 18-19 are rejected under 35 U.S.C. §103 (a) as being unpatentable over Pietsch, et al. (U.S. 4,778,461). Applicants respectfully traverse the rejection.

Claims 18-19 are rejected under 35 U.S C. 103(a) as being unpatentable over Pietsch, et al.

As noted by the Examiner, Pietsch, et al. Teach that the crosslinked silicone rubber (polydimethylsiloxane) is particularly suitable, having high fatigue strength in alternate bending as well as a high breaking strength of at least 8 N/mm^2 at a low Shore A hardness of 23-35, and an elongation at break of more than 400% (column 4, lines 55-68 and column 5, lines 1-15. Because Pietsch, et al. teach that the

crosslinked elastomer has high fatigue strength in alternate bending as well as a high breaking strength at a low Shore A hardness, and an elongation at break of more than 400%, the Examiner has taken the position that the leaflet of Pietsch, et al. can be bent about 60 degrees for about 400 million cycles without significant structural failure.

On the other hand, claims 18-19 refer to the bending of both components of the composite, the substrate and the polymer, i.e., inorganic substrate and polymer, and not just the bending of the polymeric component of the composite, such as the polymer, as clarified before. Therefore, the Examiner's position with respect to whether or not the Pietsch leaflets would be expected to bend 400 million cycles are not on point, especially when Pietsch et al specifically disclose that the support ring "supports only the lower part of the valve, whereas the upper part of the cusps and their joining zones (the commissure) remains free and flexible", thus only the polymer portion is flexible. Col. 1, lines 60-68.

Specifically, Pietsch et al do not teach or suggest a **composite** that can bend 100 degrees without exceeding its elastic limit. Due to this deficiency in the Pietsch patent with respect to the present invention, the Pietsch patent does not render claims 18 and 19 obvious. Applicants respectfully request withdrawal of the rejection of claims 18 and 19 under 35 U.S.C. §103(a) as being unpatentable over the Pietsch patent.

II. Claim 20 is rejected under 35 U.S. C. 103 (a) as being unpatentable over Pietsch, et al. as applied to claims 18-19 above, and further in view of Sumitomo Electric Co. (Abstract, JP 59192366).

Applicants respectfully traverse the rejection.

As admitted by the Examiner, Pietsch et al fail to teach a diamond-like carbon coating over at least a portion of the silicone or urethane polymer. The Sumitomo abstract discloses a diamond-like carbon on a heart valve prosthesis. As noted above, Pietsch et al do not disclose a composite with an inorganic substrate and a polymer at least partly covering the substrate that can bend 100 degrees without extending past its elastic limit. On the contrary, Pietsch et al teach that the support ring "supports only the lower part of the valve, whereas the upper part of the cusps and their joining zones (the commissure) remains free and flexible. Col. 1, lines 60-68. The function of the

support ring is to provide support to the flexible cusps and thus to prevent flapping over of the valve and to make provision for anchoring the suture ring. Col. 3, lines 15-19. The Sumitomo abstract similarly does not teach a composite of the present claim.

Three criteria must be met to establish a *prima facie* case of obviousness. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success. Finally, the prior art reference, or combination of references, must teach or suggest all the claim limitations. MPEP § 2142. Applicants respectfully submit that since neither of the cited references teach or suggest the claimed composites, the combined disclosures of the Pietsch patent and the Sumitomo abstract do not render the present invention obvious. Applicants respectfully request withdrawal of the rejection of claim 20 under 35 U.S.C. §103(a) as being unpatentable over the Pietsch patent, as applied to claims 18 and 19, in view of the Sumitomo abstract.

III. In paragraph 10 on page 3 of the Office Action, claims 3 and 31 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Cromie in view of Reul, et al. (U.S. 4,263,680).

Applicants respectfully traverse the rejection.

As discussed above, Cromie does not teach the subject matter of claim 1. As admitted by the Examiner, Cromie does not teach claims 3 and 31. Any deficiency in the teaching of Cromie is not cured by the teaching of Reul, et al. As characterized by the Examiner, Ruel, et al teaches that ceramic can be used instead of metal (col. 4, lines 20-55). However, Cromie does not teach nor suggest how to combine its teaching with that of Ruel, et al. to arrive at the subject matter of claim 1, from which claims 3 and 31 depend.

As noted above, three criteria must be met to establish a *prima facie* case of obviousness. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success. Finally, the prior art reference, or combination of references, must teach or suggest all the claim limitations. MPEP § 2142. Applicants respectfully submit that

the prior art fails to disclose all the claim limitations and there would be no motivation to combine the references as proposed by the Examiner. At the same time, even if the references were combinable, which Applicants by no means concede, the combined teachings do not teach the subject matter of claims 3 and 31. Applicants respectfully request that the rejection of claims 3 and 31 under 35 U.S.C. § 103(a) as being unpatentable over Cromie in view of Reul, et al. be withdrawn.

II. In paragraph 11 on page 4 of the Office Action, claims 6-7 and 9 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Cromie in view of MacGregor.

Applicants respectfully traverse this rejection.

As discussed above, Cromie does not teach the subject matter of claim 1. Thus, Cromie also does not teach dependent claims 6-7 and 9, which are dependent from independent claim 1, as admitted by the Examiner. Any deficiency in the teaching of Cromie is also not cured by the teaching of MacGregor.

As noted by the Examiner, MacGregor teaches a heart valve made from a combination of metal substrate and rigid porous plastic coating having a thickness of 20 to 300 microns. Col. 3, lines 20-30 and col. 4, lines 30-50. The polymer may be attached by flowing into the metal substrate thus forming a barb or anchor. Col. 5, lines 5-50.

The three criteria for establishing a *prima facie* case of obviousness are not met in this case. First, there was no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there is no reasonable expectation of success. Finally, the combination of references fail to teach or suggest all the claim limitations. MPEP § 2142. Even if assuming arguendo, that they are combinable, which Applicants by no means concede, the combined teachings do not arrive at the subject matter of claim 1. As claims 6-7 and 9 are dependent from claim 1, the combined references do not teach the subject matter of these dependent claims. Applicants respectfully request that the rejection of claims 6, 7, and 9 under 35 U.S.C. § 103(a) as being unpatentable over Cromie in view of MacGregor should be withdrawn.

In view of the amendments and reasons provided above, it is believed that all pending claims are in condition for allowance. Applicants respectfully requests favorable reconsideration and early allowance of all pending claims.

If a telephone conference would be helpful in resolving any issues concerning this communication, please contact Applicants' attorney of record, Hallie A. Finucane at 952.253.4134.

Respectfully submitted,

Altera Law Group, LLC

Date: April 25, 2003

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Appendix A
Marked Up Version of the Entire Claim Set

The entire set of pending claims is provided for the Examiner's convenience.

1. (Amended Twice) A medical device comprising a composite having an inorganic substrate and a polymer covering at least a portion of the substrate, the polymer forming a structure substantially different from the structure of the substrate [and the polymer being rigid] , and providing the form of the device.

2. (Unchanged) The medical device of claim 1 wherein the inorganic substrate comprises metal.

3. (Unchanged) The medical device of claim 1 wherein the inorganic substrate comprises a ceramic.

5. (Unchanged) The medical device of claim 1 wherein the polymer is selected from the group consisting of polyetheretherketones, polyacetals, polyethersulfones, polyarylsulfones, polyetherimides, polycarbonates, and polysulfones.

6. (Unchanged) The medical device of claim 1 wherein the polymer has an average thickness of at least about 10 microns.

7. (Unchanged) The medical device of claim 1 wherein the polymer has an average thickness from about 100 microns to about 2000 microns.

8. (Unchanged) The medical device of claim 1 wherein the medical device comprises a heart valve prosthesis, the heart valve prosthesis comprising a component that comprises the composite having the inorganic substrate and the polymer material.

9. (Unchanged) The medical device of claim 1 wherein the polymer material has structure forming a slot, hole, pin, button, barb or anchor.

10. (Unchanged) A medical device comprising a flexible composite component comprising an inorganic substrate and a polymer member covering at least a portion of the substrate, wherein the flexible composite component can be bent at least about 100 degrees without extending the flexible composite component beyond its elastic limit.

11. (Unchanged) The medical device of claim 10 wherein the inorganic substrate comprises a metal foil with a thickness less than about 500 microns.

12. (Unchanged) The medical device of claim 10 wherein the polymer is selected from the group consisting of polyurethanes, polydimethylsiloxanes and polytetrafluoroethylenes.

13. (Unchanged) The medical device of claim 10 wherein the polymer member has a thickness from about 10 microns to about 500 microns.

14. (Unchanged) The medical device of claim 10 wherein the polymer member has a thickness from about 50 microns to about 300 microns.

15. (Unchanged) The medical device of claim 10 wherein the medical device comprises a heart valve prosthesis and the composite component comprises leaflets.

16. (Unchanged) The medical device of claim 10 wherein the flexible composite component can be bent about 180 degrees without extending the flexible composite component beyond its elastic limit.

17. (Unchanged) The medical device of claim 10 wherein the flexible composite component can be bent about 180 degrees with a radius of curvature of about the thickness of the composite without extending the flexible composite component beyond its elastic limit.

18. (Unchanged) The medical device of claim 10 wherein the flexible composite component can be bent about 60 degrees for about 40 million cycles without significant structural failure.

19. (Unchanged) The medical device of claim 10 wherein the flexible composite component can be bent about 60 degrees for about 400 million cycles without significant structural failure.

20. (Unchanged) The medical device of claim 10 wherein the composite further comprises a diamond-like carbon coating over at least a portion of the polymer.

31. (Unchanged) The medical device of claim 1 wherein the polymer is crosslinked.

32. (New) The medical device of claim 1 wherein the polymer is rigid.